FDA 510(k) Premarket Notification

# K233543 YSIO X.pree

**CLEARED**

May 21, 2024
200 days to decision

K233543 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k233543/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Stationary (KPR) |
| Date received | Nov 3, 2023 |
| Decision date | May 21, 2024 |
| Days to decision | 200 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Siemens Medical Solutions** |
| Location | Danvers, MA, US |
| Contact | Camila Rodriguez Valentin |
| 510(k) history | 15 submissions · 15 cleared · 2003-2025 |